DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 12, 2014

BrosMed Medical Co., Ltd
% Stephen Lee
Deputy General Manager
15th Building, SMEs Venture Park
SongShan Lake Hi-Tech Industrial Development Zone
Dongguan 523808 CHINA

Re: K141025
Trade/Device Name: Artimes Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1340
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: August 15, 2014
Received: August 18, 2014

Dear Mr. Lee,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141025

Device Name
Artimes Balloon Dilatation Catheter

Indications for Use *(Describe)*
The Artimes Balloon Dilatation Catheter is indicated for:

1. Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion

2. Balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR 807.92(c).

Submitter:	BrosMed Medical Co., Ltd 15th building, SMEs Venture Park SongShan Lake Hi-Tech Industrial Development Zone Dongguan 523808, China Office: +86 (769) 2289 2018 Fax: +86 (769) 2289 2016
Contact Person:	Stephen Lee
Date Prepared	April, 06th, 2014
Trade Name:	Artimes Balloon Dilatation Catheter
Common Name:	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Classification Name:	Catheters, transluminal coronary angioplasty, percutaneous (21 CFR 870.5100(a), Product Code LOX)
Predicate Devices:	Sprinter Legend RX (P790017 S096; cleared October 31, 2008) Voyager RX (P810046 S216; cleared June 18, 2004) Maverick (P860019 S160; cleared September 27, 2000) Apex (P860019 S208; cleared November 7, 2008) Fire Star (P880003 S090; cleared August 31, 2007)
Device Description:	The Artimes[1] (Rx type) device is a coronary dilatation catheter designed for easy guidewire exchange. The catheter working length is 140cm. Lubricious coatings are applied to the distal section. Balloon diameters range from ∅1.5mm to ∅4.0mm. The balloon material is made of a semi-compliant Pebax material for diameter 1.5mm to 4.0mm with a rated burst pressure of 14 atmospheres. The proximal shaft of the catheter is composed of a female luer connector bonded to a PTFE coated stainless steel tube with a wire. The proximal shaft joins with a smooth transition to a distal shaft composed of an outer tube of pebax/nylon and a tri-extrusion inner tube with a balloon laser welded to both tubes at the distal tip. Two radiopaque platinum/iridium marker bands are located within the balloon segment with the exception of balloon diameters less than 2.0mm which incorporate a centrally positioned single marker band. The inner tube accepts a standard 0.014 inch PTCA guidewire. The guide wire enters the catheter's tip and advances coaxially out the distal Rx port, thereby allowing both coaxial guidance and rapid exchange of catheter with a single standard length guide wire. Two marked sections of 5mm length each located on the proximal shaft indicate catheter position relative to the tip of either a brachial or femoral guiding catheter. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements. Note 1: the Artimes balloon dilatation catheter family contains ∅1.0-1.25mm x 5-30mm configurations which are NOT intend for sales in the United States (US) but rest of world (ROW) based upon availability of regulatory approvals. Separate Catalog numbers have been assigned to the Artimes US product (801-DDLLU, reference section 11.0) for the ∅ 1.5-4.0mm x 5-30mm configurations with its IFU and label, compared with Artimes ROW product (801-DDLL) for the ∅1.0-4.0mm x 5-30mm configurations. Additional 510k

or relevant (e.g. IDE or PMA) submission will be executed if BrosMed Medical is going to registry those configurations (∅1.0-4.0mm x 5-30mm) in the United States.

Intended Use:

The Artimes PTCA catheter is indicated for:

- balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion
- balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction

Technological Characteristics:

Comparisons of the new and predicate devices show that the technological characteristics such as product performance, design, and intended use are substantially equivalent to the currently marketed predicate devices.

Performance Data:

Both *in vitro* performance tests, such as dimensional verification, balloon preparation, deployment, and retraction, balloon rated burst pressure, balloon fatigue, balloon compliance, balloon inflation and deflation time, catheter bond strength, tip pull strength, flexibility and kinking, torque strength, radiopacity, coating integrity, and particulate evaluation, and also biocompatibility tests, such as cytotoxicity, sensitization, hemocompatibility, pyrogenicity, acute systemic toxicity, intracutaneous reactivity and genototocity (bacterial mutagenicity and in vitro mouse lymphoma) were conducted on the Artimes PTCA catheter. The test results met all acceptance criteria, were similar to predicate devices, and ensure that the Artimes PTCA catheter design and construction are suitable for its intended use as recommended by the Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (FDA; September 8, 2010).

Conclusion:

This information supports as determination of substantial equivalence between the Artimes PTCA catheter and the predicate devices described above.